Instructions
for Use

smith&nephew

EXOGEN 4000+◇
Ultrasound Bone Healing System

CAUTION
Federal Law (U.S.A.) restricts this device to sale, distribution, or use by or on the order of a physician or properly licensed practitioner. The device is only intended for use by the individual for whom it is prescribed.

Equipment Classification and Device Symbol Descriptions

	Information Symbol: refer to Instructions for Use.
	Type B Applied Part
CE 0086	CE Mark: indicates conformity with European Council Directive of 14 June 1993 concerning Medical Devices (93/42/EEC).
	EU: Not for General Waste This symbol indicates that this device should not be disposed of with ordinary household waste at the end of its life. For details on how to dispose of this device correctly, contact your local government waste disposal agency or your local Smith & Nephew representative.
	Manufacturer
EC REP	EC Rep Symbol: indicates the authorized representative in the European Community
SN	Serial number (first four digits of the serial number indicate the month and year of manufacture)
Rx only	Rx Symbol: Federal Law (U.S.A.) restricts this device to sale, distribution, or use by or on the order of a physician or properly licensed practitioner. This device is only intended for use by the individual for whom it is prescribed.

EXOGEN® is a Class B digital apparatus which meets all requirements of the Canadian Interference-Causing Equipment Regulations. EXOGEN est un appareil de classe B qui répond a toutes les exigences des Régulations Canadiennes sur les équipements pouvant causer des interférences.

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For additional information on the EXOGEN device, please visit our website at www.exogen.com

THIS DEVICE IS NON-STERILE.
IT DOES NOT REQUIRE STERILIZATION PRIOR TO USE.

Introduction to the EXOGEN 4000+◇ Ultrasound Bone Healing System

The EXOGEN 4000+ Ultrasound Bone Healing System provides a non-invasive therapy for healing non-unions or accelerating the healing of fresh fractures. The EXOGEN device delivers safe, low-intensity pulsed ultrasound through a coupling gel to a broken bone. The low-intensity pulsed ultrasound has been shown in laboratory studies to stimulate cells to produce growth factors and proteins that are important to bone healing.

PLEASE BE SURE TO READ THE ENTIRE MANUAL BEFORE USING The EXOGEN 4000+ Ultrasound Bone Healing System.

Indications for Use

The EXOGEN 4000+, or any other EXOGEN Ultrasound Bone Healing System is indicated for:

- The non-invasive treatment of established non-unions† excluding skull and vertebra.
- Accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius fractures (fractures of the end of the large bone in your forearm) and fresh, closed or Grade I open tibial diaphysis fractures (fractures in the middle 80% of the large bone in your lower leg) in skeletally mature individuals when these fractures are orthopaedically managed by closed reduction and cast immobilization (adult individuals eighteen years of age or older who have fractures, with or without minor skin wounds, that are placed in a cast for treatment).

†A non-union is considered to be established when the fracture site shows no visibly progressive signs of healing.

Contraindications

There are no known contraindications to the use of this device.

Warnings

The safety and effectiveness of the use of this device has not been established for:

- Fractures with post-reduction displacement of more than 50% (i.e., fractures in which the opposing broken bone ends are out of alignment by more than one half of the width of the bone).
- Pathological fractures due to bone pathology or malignancy (fractures due to disease)
- Pregnant or nursing women
- Individuals with thrombophlebitis (blood clot in a vein), vascular insufficiency (poor blood supply), abnormal skin sensitivity (very sensitive skin), sensory paralysis (lack of sensation), alcoholism and/or nutritional deficiency.
- Individuals receiving steroid, anti-coagulant, prescription

Warnings (continued)

- non-steroidal anti-inflammatory, calcium channel blocker and/or diphosphonate therapy. Individuals using these therapies were excluded from the studies because of the possible effects of these therapies on bone metabolism.
- Non-unions of the vertebra and the skull
- Individuals lacking skeletal maturity
- Fresh fracture locations other than the distal radius (end of the large bone in the forearm) or tibial diaphysis (middle 80% of the large bone in your lower leg).
- Fresh fractures that are open Grade II or III (fractures with large wounds) or that require surgical intervention with internal or external fixation (screws and/or plates used to hold your broken bones in place) or that are not sufficiently stable for closed reduction (manipulation of the fracture without surgery) and cast immobilization (cast treatment)

Precautions

- The device will not correct or alter post-reduction (when your fracture is initially set and placed in a cast) aspects of a fracture such as displacement, angulation or malalignment.
- The operation of active, implantable devices, such as cardiac pacemakers may be adversely affected by close exposure to the EXOGEN® device. The physician should advise the patient or other person in close proximity during treatment to be evaluated by the attending cardiologist or physician before starting treatment with the EXOGEN device.
- Cell phones, televisions, and other devices using radio-frequency energy may cause interference. While the EXOGEN device complies with the limits for Class B digital devices pursuant to Part 15 of the FCC rules, it has not been studied with all brands and models of phone.
- The safety and effectiveness of the EXOGEN device when used for more than one daily 20 minute treatment period has not been studied. Patients in the clinical studies were instructed to apply the device for one treatment period of twenty-minutes each day.
  - The age ranges of the patients in the PMA non-union studies were 17-86. The effect of EXOGEN therapy on patients outside this age range has not been studied.
  - The age ranges of the patients in the PMA fresh fracture studies were 17-67. The effect of EXOGEN therapy on patients outside this age range has not been studied.
- The safety and effectiveness of the use of this device has been demonstrated for patients followed up over a period of 6.5 years (78 months).

Complications

No device related adverse reactions or medical complications related to the use of this device were reported during the clinical studies. Some patients have experienced mild skin irritation caused by skin sensitivity to the coupling gel. Resolution can be obtained by a change of coupling medium to mineral oil or glycerin. In the distal radius study, one patient complained of pain during treatment but this resolved by the next follow up visit and one patient, complaining of pain, withdrew from the study.

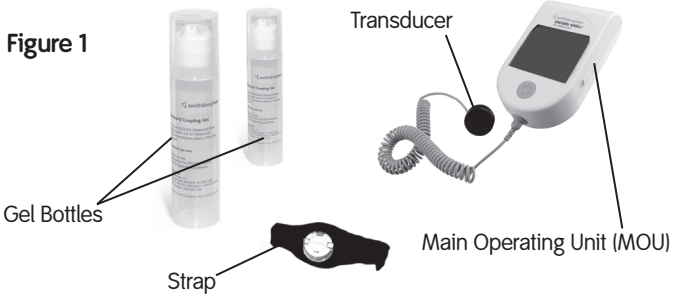
Adverse Events

The ultrasound intensity is comparable to diagnostic ultrasound, such as the intensities used in obstetrical sonogram procedures (fetal monitoring). Unlike conventional (physical therapy) ultrasound devices, the EXOGEN® device is incapable of producing harmful temperature increases in body tissue. In addition, there is no evidence of non-thermal adverse effects.

Device Description

The EXOGEN device is designed for ease of use at home, and is comprised of a main operating unit with a permanently connected transducer, a strap, and coupling gel (see figure 1). It is lightweight and portable with a large visual display and audible tones to give information during treatment.

Figure 1



Use the EXOGEN device for 20 minutes a day, or as prescribed by a physician. You should continue using the EXOGEN 4000+ device until your physician determines that your fracture is sufficiently healed.

The intensity of the ultrasound signal is low, similar to diagnostic ultrasound intensities used in sonograms (fetal monitoring).

The main operating unit provides the treatment control circuitry, the primary battery supply, and also monitors the operation of the transducer at the fracture site. To ensure the device is functioning properly, the EXOGEN device main operating unit constantly monitors the ultrasound signal delivery. The unit is functioning correctly if the numbers are counting down. If at any time the device stops functioning properly, an Attention signal ⚠ will appear on the screen. Neither you nor your physician can change the ultrasound specifications or service the device.

System Components

The Main Operating Unit (MOU) is powered by a non-replaceable lithium battery. The MOU self monitors, controls system operation during treatment, and verifies correct operation of the transducer. The device monitors the presence/absence of coupling gel on the transducer surface and alerts the patient with an audible beep if gel is not present. The MOU maintains a complete record of patient daily use of the device, which is available to the physician. The transducer transmits low intensity pulsed ultrasound to the skin at the fracture site through a coupling medium.

The gel bottles supplied with the device contain the appropriate ultrasound coupling gel. Alternatively, mineral oil or glycerin can be substituted for the gel provided.

Note: EXOGEN® Ultrasound coupling gel supplied is the recommended gel for use with this system. Do not substitute other gels as they may damage the transducer surface or impede signal transmission. Please call the Clinical Therapies Service Center, 1-800-836-4080 of Smith & Nephew, Inc., if you need more coupling gel.

The Strap is designed to hold the transducer over the fracture site. When closed, it applies light pressure to the top of the transducer to maintain skin contact.

Treatment Schedule

Device Life

The EXOGEN device is powered by a non-replaceable, non-rechargeable lithium battery pack with a life of a minimum of 150 treatments of 20 minutes each. If your EXOGEN device requires a battery service before your fracture is healed, please call the Clinical Therapies Service Center, 1-800-836-4080.

Treatment Time

The EXOGEN device should be worn for 20 minutes per day, or as prescribed by your physician. The EXOGEN 4000+ device will count down the 20 minutes of treatment time when you push the On/Off button, and it will automatically shut itself off with an audible beep when the 20 minute treatment is complete. The device also has an internal patient usage monitor that records the date and time of each treatment. This record can be made available to your physician so that he or she can monitor your compliance. Your physician will determine when your fracture is healed. Each patient and fracture is unique, and it takes some fractures longer to heal than others.

Note: The 20 minute treatment time may be interrupted for up to 30 seconds if necessary. Do not push the orange On/Off button. Remove the transducer from your skin, attend to your interruption, reapply coupling gel to the transducer as necessary, and return the transducer to your skin. If the interruption is longer than 30 seconds, the device will turn off, and you will need to begin a new 20 minute treatment.

Visual and Audio Indicators

Symbol/Alarm	Description	Meaning / Next Steps
	Attention symbol shown with a beeping tone lasting for 30 seconds, then the device turns off.	Meaning: The device has encountered a fault condition. Next Steps: Wait 1 minute. Turn the device on by pressing the orange On/Off button. If the device still displays the Attention symbol, call Smith & Nephew Customer Services for service (see Service).
	Add Gel symbol blinks with a beeping tone that lasts for 30 seconds, then the device turns off.	Meaning: Add coupling gel to the transducer face. Next Steps: Remove the transducer from the strap or cast. Add one pump of coupling gel to the transducer face that will touch your skin. Place the transducer to your skin in the strap or cast. If the device has turned off, press the orange On/Off button.
	Pulsing Treatment symbol which pulses as the timer counts down	Meaning: Ultrasound treatment is being delivered and device is functioning properly
	Treatment Stop symbol displays briefly with 2-tone beep, and device turns off.	Meaning: 20 minute treatment has been completed.
	Digital numbers displayed on screen	Meaning: Device is running a 2-second self test.
	Digital numbers displayed on screen	Meaning: Device is counting treatment time down from 20 minutes.

Device Application

Before you begin treatment with the EXOGEN 4000+◇, your physician will place a mark on your skin over your fracture to indicate where you should position the EXOGEN 4000+ transducer.

To begin a 20 minute treatment with the EXOGEN 4000+ you will need:

- The EXOGEN 4000+ main operating unit
- A bottle of EXOGEN coupling gel
- The strap

Positioning the Strap

1. Hold the strap with the EXOGEN cap side up, and pull the end of the strap up through the bottom of the loop. (Figure 2)
2. Using 2 fingers, gently squeeze the flanges on the sides of the cap to open the cap. (Figure 3)
3. Position the strap so the cap is placed directly over the fracture site as marked by your physician. (You should be able to see the mark on your skin through the round opening). (Figure 4)
4. Tighten the strap utilizing hook and loop to hold position. Be careful not to overtighten.

Figure 2

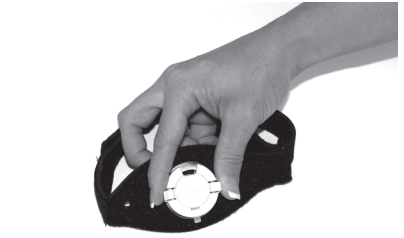


Figure 3

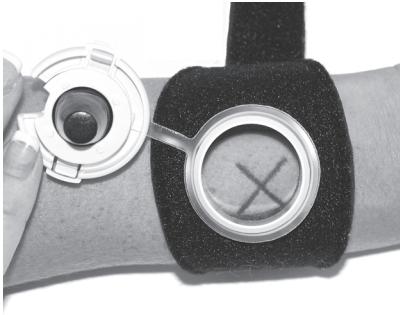


Figure 4

Applying the Device when you have a Cast

Your physician or cast technician will prepare your cast for EXOGEN® treatment by installing the plastic cap assembly into your cast.

1. Using 2 fingers, gently squeeze the flanges on the sides of the cap installed in your cast, and open the cap (as indicated in Figure 3 on the previous page).
2. Remove the round felt plug from the cast opening. (Figure 5)

Figure 5

Applying Coupling Gel

1. Remove the top from the coupling gel bottle.
2. Hold the transducer where the cable meets the transducer.
3. Place your finger on the gel bottle pump and press down to apply one pump of gel onto the transducer face. (Note: The first time you use the gel, you may need to pump a few times to get the gel flowing) (Figure 6)
4. Place the transducer into the cap opening. The gel should be touching the skin. (Figure 7)
5. Align the cord in the U shaped cutout in the cap, and snap the cap closed on the strap or on the cast. (Figure 8 & 9)
6. Replace the top on the gel bottle.

Figure 6

Figure 7

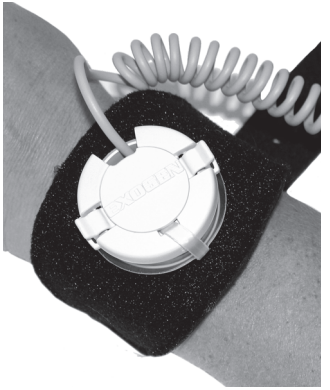


Figure 8

Figure 9

Device Operation

Turning the Unit On and Off

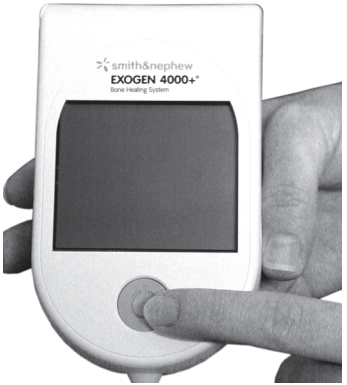


Figure 10

Firmly press then release the orange “On/Off” button on the EXOGEN 4000+◇ to turn the device on. (Figure 10) When the device is on, a sequence of status symbols will display momentarily as follows:

1. The device will emit a 2-tone beep and show all the symbols on the display at once while it runs a 2-second self test.
2. The device will then display the total number of COMPLETE treatments delivered.
3. The device will then display the total number of PARTIAL treatments.
4. The device will then start ultrasound treatment. The timer countdown begins at 20 minutes, and there will be a Pulsing Treatment symbol.
5. The unit is delivering ultrasound provided the numbers are counting down.

Once the 20 minute treatment countdown has reached zero, the device will emit a 2-tone beep and turn itself off.

When Treatment is Complete

1. Open the cap.
2. Remove the transducer and clean any excess gel with a soft cloth. (Figure 11)

Figure 11

3. Remove the strap and clean any excess gel from your skin and strap. (Figure 12)

Figure 12

If using with a cast:

a. Carefully clean any excess gel from your cast.
b. Replace the round felt plug, with the tab on top, into the cap opening. This is important to prevent swelling in the cast opening when you are not using EXOGEN®. (Figure 13)

4. Place unit and accessories into EXOGEN system tote until the next treatment time.

Figure 13

Care and Cleaning

While the EXOGEN 4000+ Ultrasound Bone Healing System has been designed for your ease of use, it does incorporate complex electronic technology to deliver its low-intensity pulsed ultrasound treatment and should be handled with care. Please note the following:

- Do not attempt to modify or repair the EXOGEN device. There are no user serviceable parts inside the device.
- Use only a clean soft cloth, paper towel, or cotton swab to clean the transducer or strap. Do not use cleaning agents or solvents on any of the components of the system.
- Never immerse the unit in water.

Care and Cleaning (continued)

- Do not expose the EXOGEN® device to extreme temperatures or the internal electronic components may be damaged.
- Exercise care when handling the transducer as rough handling may adversely affect the device's operation.
- Do not store near radiators or extreme heat.
- As with any home electronic device, protect the EXOGEN 4000+ device from impact, exposure to moisture, liquid spills, sand, dirt or debris.
- Periodically inspect the cable and the transducer for any cracks or signs of damage.

Operation, Storage, and Transport

The EXOGEN device should be operated within:
Ambient temperature range: 50°F (10°C) to 104°F (40°C)
Relative humidity range: 30% to 75%
Atmospheric pressure range: 700 hPA to 1060 hPA

The EXOGEN device should be stored and transported within:
Ambient temperature range: 32°F (0°C) to 122°F (50°C)
Relative humidity range: 30% to 75%
Atmospheric pressure range: 700 hPA to 1060 hPA
If the device is stored or transported in temperatures outside this range, allow the device time to come to room temperature before operating.

Interference with proper operation of the EXOGEN 4000+ device may occur in the vicinity of equipment such as portable and mobile communication units marked with this symbol.

If abnormal operation of the device is observed, attempt to relocate or reorient the device in relation to the interfering equipment.

Disposal

Follow your local refuse laws to dispose of the EXOGEN 4000+ unit. The EXOGEN unit is for single patient use ONLY. Dispose of batteries properly to prevent injury. Do not throw into fire.

Service

Smith & Nephew Clinical Therapies Service Center is available to answer questions regarding use of the EXOGEN 4000+° device and to handle any servicing needs. Call 1-800-836-4080, option #2.

If your unit shows the Attention symbol or otherwise needs service, please follow these instructions:

1. Call Smith & Nephew Clinical Therapies Service Center, describe the problem, and request a Return Authorization (RA) number.
2. Pack the device in its original packaging. Otherwise pack the device to prevent movement during shipping.
3. Label the box with this address: Smith & Nephew Inc, 1450 E. Brooks Rd, Memphis TN 38116
4. Complete the shipper airbill supplied with your device, and contact the freight company to arrange pickup.

To Contact Smith & Nephew Clinical Therapies Service Center:
In the United States:
Call 1-800-836-4080, option #2
In the European Community:
Call (+49) 746-22080
In all other countries
Call (+1) 901-396-2121 (USA) and ask for Clinical Therapies Service Center

Questions regarding where to place the device for treatment, fracture healing, issues with casts or other medical issues should be addressed to your physician.

Authorized European Community (EC) Representative:
Smith & Nephew
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